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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,288	07/06/2001	Paul F. Goetinck	10284-029001 / MGH 1733.1	6095
26161	7590	02/25/2004	EXAMINER YAEN, CHRISTOPHER H	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/900,288

## Applicant(s)

GOETINCK, PAUL F.9

## Examiner

Christopher H Yaen

## Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,7-11 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-11 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. The amendment filed 11/26/2003 is acknowledged and entered into the record. Accordingly, claims 2-6, and 12-16 are canceled without prejudice or disclaimer.
2. Claims 1, 7-11, and 17-19 are pending and examined on the merits.

***Claim Rejections Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

3. The rejection of claims 1, 7-11, and 17-19 under 35 USC 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the instant disclosure provides “proof *in vivo* that reducing syndecan-4 inhibits angiogenesis”, and the references cited to show unpredictability of the animal models is in no way any indication of whether the administration of syndecan-4 reducing agents would not work. It is further stated, by the applicant that the mechanism by which the reducing agents inhibit angiogenesis is irrelevant provided that the administration of the said agents actually inhibits angiogenesis. Applicant’s arguments have been carefully considered but are not deemed persuasive. Although it is true that the applicant is claiming a method of inhibiting angiogenesis and that the mechanism by which this occurs is not needed, the specification has not provided the skilled artisan with any information with regard to the actual administration of the said reducing agents. The specification lacks any enabling disclosure with regard to the how theses agents when administered are able to inhibit angiogenesis, and the specification has not provided any nexus between the findings of the knockout mouse and the administration or effects of the said agents. Furthermore, given the unpredictable nature of the phenotypes

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generated from knock-out-mice, one of skill in the art cannot with any certainty practice the invention commensurate in scope with the claims because the specification has not provided any guidance in the form of working examples for the actual administration of the said agents.

In addition, applicant argues that Kerbel *et al* provides support with regard to the use of angiogenesis inhibitors and further states that "some drugs...can induce stable disease", and that the such stable disease is a desirable outcome of anti-angiogenesis treatment. Although it is true that reduction of tumor spreading, by preventing angiogenic vessel formation, is considered a success outcome of anti-angiogenesis treatment, the specification has not actually taught how such treatments with the syndecan-4 reducing agents is to be accomplished or whether such agents fall within the drugs that work and those that do not work. Kerbel *et al* points out that others have found that the use of anti-angiogenesis drugs actually increased blood flow to the tumor (see page 730). There is no indication that the administration of the syndecan-4 reducing agents claimed would not have such an effect, because no disclosure or working examples which addresses this question have been put forward for the skilled artisan to determine, thereby resulting in undue experimentation. Further, Kerbel *et al* points out that although there are many promising outcomes associated with the use of anti-angiogenic drugs, more understanding of the complex mechanism of blood vessel formation and the need for adequate markers for the determination of efficacy are still required before there is successful treatment of tumors with anti-angiogenic therapies.

Therefore, given the lack of disclosure with regard to the use of syndecan-4 reducing agents, the lack of correlation between the findings in the mouse model and the actual use of the reducing agents, and the unpredictable use of anti-angiogenesis agents in general

### ***Conclusion***

4. No claim is allowed.
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

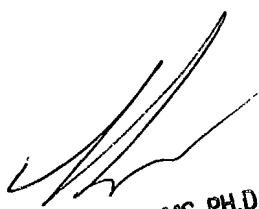
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1642  
February 10, 2004



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER